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LATHAM & WATKINS LLP

April 21, 2021

VIA ECF

The Honorable Philip M. Halpern
United States District Judge
Southern District of New York
500 Pearl Street, Room 1950
New York, New York 10007

Re: *Allele Biotechnology and Pharmaceuticals, Inc.*
No. 7:20-cv-08255 (PMH) (AEK) (S.D.N.Y.)

Application for pre-motion conference granted.

The Court shall hold a telephonic pre-motion conference on June 3, 2021 at 09:30 a.m. At the time of the scheduled conference, all parties shall call: (888) 398-2342; access code: 3456831.

The Clerk of the Court is respectfully directed to terminate the motion sequence pending at Doc. 30.

SO ORDERED.

Philip M. Halpern
United States District Judge

Dated: White Plains, New York
April 29, 2021

Dear Judge Halpern:

We write on behalf of Regeneron Pharmaceuticals, Inc. ("Regeneron") pursuant to Rules 2(C) and 4(C)(iii) of Your Honor's Individual Practices to request a pre-motion conference for permission to file a motion to dismiss Plaintiff Allele Biotechnology and Pharmaceuticals, Inc.'s ("Allele") Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6).

Safe Harbor. In late 2019, SARS-CoV-2, the virus that causes COVID-19, spiraled the world into a global pandemic. Regeneron responded immediately, shifting resources to the discovery of a potentially life-saving treatment. Applying successful viral platforms it already had in place, Regeneron swiftly developed a groundbreaking antibody cocktail, REGEN-COV, for patients infected with the virus and at high risk for severe illness and/or hospitalization. This therapy has already treated many people, including the former President of the United States, and Regeneron's drug continues to be critical in the pandemic response. But Allele, through its lawsuit, recasts a simple and replaceable supporting laboratory reagent into a central character, which it was not, and Allele as deserving of substantial compensation, which it is not.

Allele's Amended Complaint accuses Regeneron of infringing U.S. Patent No. 10,221,221 (the "'221 patent") based on activities Regeneron undertook in relation to its FDA

submission for REGEN-COV. Because such activities are immunized from patent infringement under 35 U.S.C. § 271(e)(1), Allele's Amended Complaint should be dismissed.

The "safe harbor" from patent infringement is codified in § 271(e)(1), which provides:

> It shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

Id. The purpose of the statute is to allow drug makers, "prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval." *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 671 (1990). The immunity has "wide berth" and "extends to all uses of patented inventions that are reasonably related to the development and submission of any information" to the FDA. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005); *see also Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1356 (Fed. Cir. 2012); *Teva Pharms. USA, Inc. v. Sandoz Inc.*, Nos. 09 Civ. 10112 (KBF), 10 Civ. 7246 (KBF), 2013 WL 3732867, at *2, *6 (S.D.N.Y. July 16, 2013) (recognizing the safe harbor's "wide berth," rejecting any exemption for "research tools" under *Proveris*, and granting a motion to dismiss under § 271(e)(1)).

The Supreme Court has made clear that information is not excluded from safe harbor protection based on the "phase of research in which it is developed," or whether it is "ultimately submitted to the FDA" and "necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process." *Merck*, 545 U.S. at 202, 206. Further, "experimentation on drugs that are not ultimately the subject of an FDA submission" or "use of patented compounds in experiments that are not ultimately submitted to the FDA" are not excluded. *Id.* at 206. As such, multiple courts—including this Court—have

held that screening multiple drug candidates to identify the optimal candidate for FDA submission is protected under the safe harbor.

In *Merck*, "[a]ll of the experiments charged with infringement were conducted for the purposes of determining the optimum candidate angiogenesis inhibitor and proceeding with commercial development of the selected candidate in compliance with regulatory procedures." *Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d. 1334, 1340 (Fed. Cir. 2007). Likewise, in *Katz v. Avanir Pharmaceuticals*, defendant's use of a patented assay "to screen compounds as part of [defendant's] IgE drug development program" through which "[o]ne of these compounds was ultimately selected" for preclinical studies forming the basis for an IND was covered by § 271(e)(1). No. 06-cv-0496 DMS (LSP), 2007 WL 9776599, at *2, *6 (S.D. Cal. Aug. 21, 2007). Similarly, in *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, use of patented compound intermediates to run "hundreds of experiments for purposes of possibly identifying a drug candidate" was within the safe harbor. No. 95 Civ. 8833 (RPP), 2001 WL 1512597, at *4, *7-8 (S.D.N.Y. Nov. 28, 2001). And in *Teva*, this Court held that defendants' use of peptide markers to characterize the drug's active ingredient in generating data for FDA submission was protected by the safe harbor even though "[t]he claimed markers are not themselves drug products, nor do they need approval from the FDA." *Teva*, 2013 WL 3732867, at *2.

Perhaps given the resounding authority supporting dismissal, Allele largely relies on policy and legislative history to argue that this Court should narrow the safe harbor to exclude actions by companies, like Regeneron, that are racing to perform the tests needed to gain FDA approval for life-saving drugs during a pandemic. Apart from this flawed reliance, Allele misreads and wrongly applies the Federal Circuit's decision in *Proveris*. As this Court explained in *Teva*, the *Proveris* case "cannot be separated from its factual context." *Teva*, 2013 WL

3732867, at *8. *Proveris* simply recognizes that the safe harbor does not protect use by a third party not itself engaged in developing information for FDA submission. *Id.*

This purely legal question is case dispositive. Allele's Original Complaint alleged infringement based on Regeneron's purported use of a protein called mNeonGreen (allegedly covered by the '221 patent) to determine the optimal candidates for FDA submission. (*See also* Am. Compl. ¶¶ 29-33, Ex. B at 3, 4.) In an attempt to muddy the waters, Allele's Amended Complaint adds conclusory and baseless allegations—*upon information and belief*—regarding "post-approval" uses and uses unrelated to FDA submission. (*See id.* ¶¶ 34-38.) But Regeneron's product is not even approved yet, such that there can be no "post-approval" uses. Nor can disclosure in a patent application of the same data for FDA submission or the potential co-existence of a commercial purpose repeal the safe harbor exemption. *See Classen Immunotherapies, Inc. v. Elan Pharms., Inc.*, 786 F.3d 892, 897-98 (Fed. Cir. 2015) (subsequent use or disclosure of data in patent application does not repeal safe harbor exemption); *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997) (safe harbor allows use of data "for more than FDA approval" and "intent or alternative uses are irrelevant").

In short, the activities alleged in Allele's Amended Complaint plainly fall under the "wide berth" and "expansive" protection recognized by *Merck, Momenta*, and *Teva*, and are analogous to the preclinical testing of candidates deemed protected by § 271(e)(1) in *Merck*, *Katz*, and *BMS*.[1] At a minimum, the Court should dismiss Allele's allegations as to Regeneron's

[1] Contrary to Allele's legal contentions, § 271(e)(1) does not require Regeneron to seek approval for a competing fluorescent protein product, nor does Allele's patent need to be eligible for patent term extension under § 156 for the safe harbor to apply. *See Classen*, 786 F.3d at 897 ("Nor does the statute limit the safe harbor only to those activities necessary for seeking approval of a generic version of a brand-name drug product."); *Eli Lilly*, 496 U.S. at 665 (citing 35 U.S.C. § 100(a)) ("271(e)(1) is defined to include all inventions"); *Bristol-Myers Squibb*, 2001 WL

screening activities, which would significantly narrow the case and render it amenable to prompt resolution as Regeneron has represented to Allele—and represents to this Court—that it ceased using the accused technology prior to FDA's Emergency Use Authorization in November 2020, and will not use it in the future.

Willful Infringement. Allele's willful infringement allegations fail to adequately plead: (1) knowledge of the patent; (2) subjective intent to infringe; and (3) egregiousness. *See Novartis Vaccines & Diagnostics, Inc. v. Regeneron Pharms., Inc.*, No. 18-cv-2434 (DLC), 2018 WL 5282887, at *2-3 (S.D.N.Y. Oct. 24, 2018). As to knowledge, Allele fails to allege that its purported pre-suit communications even mentioned the '221 patent, and tellingly, did not attach them as exhibits. *See, e.g.*, *Verint Sys. Inc. v. Red Box Recorders Ltd.*, No. 1-14-cv-05403, D.I. 138, at 7, 9 (S.D.N.Y. Aug. 10, 2016) (dismissing willfulness allegations where complaint exhibits "contain[ed] no direct reference to [] the patent itself"). And, mere reference to willfulness "cannot alone state a claim for willful infringement." *Novartis*, 2018 WL 5282887 at *3. Instead, Allele would need to plead that Regeneron's actions were "willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate." *See Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1932 (2016). Allele effectively asks the Court to allow a willfulness claim to proceed based merely on Regeneron racing to make a lifesaving drug in a time of crisis, allegedly without accounting for a patent, when Allele did not even bother to bring that patent to Regeneron's attention. This flawed theory of willfulness should not be allowed to proceed.

1512597, at *2 ("Nothing in the text of Section 271(e)(1) indicates that Congress intended to restrict the scope of the term 'patented invention' to those products covered by Section 156."); *Momenta*, 686 F.3d at 1361 (rejecting proposition that "the safe harbor should not be available unless a patent term extension is also available").

Respectfully submitted,

/s/ Michael Morin
Michael Morin (admitted *pro hac vice)*
LATHAM & WATKINS LLP

cc: All Counsel of Record (via ECF)